

Chapter 4

Section 4.08

Ministry of Health and Long-Term Care

Health Laboratory Services

Follow-up to VFM Section 3.08, 2005 Annual Report

Background

Laboratory testing provides up to 80% of the information that physicians use to make medical decisions. Under the *Laboratory and Specimen Collection Centre Licensing Act* (Act), the Ministry of Health and Long-Term Care licenses and regulates Ontario's 185 hospital and 41 private medical laboratories, and these laboratories' 421 specimen-collection centres. In addition, the Ministry has a contract with the Ontario Medical Association (OMA) to operate a quality assurance program to monitor and improve the proficiency of licensed laboratories, which includes evaluating the quality and accuracy of testing performed in all licensed laboratories, and conducting laboratory accreditation. The Ministry inspects laboratories that have not yet been accredited.

During the 2005/06 fiscal year, the Ministry spent \$1.4 billion on laboratory services (\$1.3 billion in 2003/04), comprising hospital laboratory expenditures of \$824 million and private-sector laboratory expenditures of \$572 million. In addition, the OMA was paid \$4.4 million to operate the quality assurance program.

In our 2005 Annual Report, we noted that a scope limitation imposed by the *Quality of Care Information Protection Act* (which came into force

on November 1, 2004) prevented us from fully assessing whether the Ministry had adequate processes in place to ensure that private-sector and hospital laboratories were complying with applicable legislation and established policies and procedures. Specifically, we were prohibited from examining the OMA's quality assurance program or the Ministry's monitoring of this program after October 31, 2004, and therefore we were unable to determine whether the quality assurance program for laboratory services was functioning as intended after that time. However, we were able to determine that, for the most part, the Ministry had adequate procedures to ensure that the laboratories' specimen-collection centres were complying.

In our 2005 Annual Report, we also noted that, given the considerable responsibility that the Ministry delegates to the OMA for assessing the quality of laboratory services, it is vital that the Ministry obtain adequate information to assess whether the OMA is fulfilling its responsibilities to the degree needed to ensure quality patient care. However, on the basis of information available to October 31, 2004, we found that the Ministry was not obtaining sufficient and timely information on laboratories that performed poorly and did not ensure that timely corrective action was always being taken. Our specific concerns included:

- Although laboratories were being notified in advance that a specimen sample was part of the OMA's quality assurance program, the number of significant errors being made by the laboratories in analyzing the samples submitted to the OMA was increasing.
- The Ministry was not normally notified that a laboratory was producing inaccurate or questionable test results (that is, significant and lesser errors) for certain types of tests until the laboratory had a two- to four-year history of performing poorly on its external quality assessment tests.
- Although the Act allows laboratories in physicians' offices to conduct only *simple* laboratory procedures, a regulation under the Act effectively allows physicians to conduct *all* laboratory tests. At the time of our *2005 Annual Report*, we remained concerned that laboratories in physicians' offices were not subject to the quality assurance provisions that applied to other laboratories.
- No integrated system was in place to make laboratory test results accessible to all health-care providers, which could result in duplicate testing and delays in patient treatment.
- An inter-provincial study estimated that Ontario's per capita spending on all laboratory services in the 2001/02 fiscal year was the second highest in Canada. Despite high costs, the Ministry:
 - had not periodically reviewed or studied on an overall basis whether laboratory tests that were conducted were appropriate or necessary, even though other jurisdictions had noted concerns in these areas and had found that best-practice guidelines could significantly improve laboratory utilization; and
 - had not analyzed the underlying actual costs of providing laboratory services so that this information could be utilized in

negotiating the fees to be paid for private laboratory services.

With respect to well-water testing by public-health laboratories, we noted that the report of the results of well-water testing issued to well owners did not clearly state that well water that was reported to have no significant evidence of bacterial contamination may still be unsafe to drink because of chemical and other contaminants.

We made a number of recommendations for improvement and received commitments from the Ministry that it would take action to address our concerns.

Current Status of Recommendations

According to information received from the Ministry in spring 2007, two recommendations in our *2005 Annual Report* were substantially implemented, while some progress had been made in implementing the rest of our recommendations. Full implementation of the Ontario Laboratories Information System will take a year longer than planned. As well, our recommendation to collect better information on the costs of laboratory services to ensure that the services are being acquired economically will take one to two more years to fully implement. The current status of the action taken on each of our recommendations is as follows.

MEDICAL LABORATORIES

Monitoring of Private and Hospital Laboratories

Recommendation

To help ensure that laboratories comply with the Laboratory and Specimen Collection Centre Licensing Act and can be relied upon to produce accurate test results, the Ministry should:

- *enhance its oversight of the Ontario Medical Association's (OMA's) quality-assurance activities, including obtaining sufficient information on the results of the OMA's accreditation process, as well as significant and lesser errors found in laboratory test results and evidence that corrective action has been taken on a timely basis; and*
- *until such time as it ceases its regular inspections, conduct them consistently.*

Current Status

At the time of our follow-up, accountability agreements had been signed with the OMA, outlining the types of reports, mechanisms for reporting, and time frames for reporting to the Ministry. These accountability agreements address reporting for both the OMA's accreditation and external quality assessment work. At the time of our follow-up, the Ministry indicated it did not receive detailed information on the number of proven significant and lesser errors at each laboratory, even if the number was high, unless the OMA issued a letter of concern. However, it was receiving notification of the action taken when there was an increase in the number of lesser or significant errors at a laboratory.

Once a laboratory is accredited by the OMA, the Ministry will cease its regular inspections. The Ministry indicated that it had updated its inspection-procedures manual to reflect how laboratory inspections are to be consistently performed by all inspectors until all laboratories are accredited, which is expected to be in 2008.

Monitoring of Physicians' Offices' Laboratories

Recommendation

To help ensure that laboratory tests conducted in physicians' offices are properly performed and produce accurate results, the Ministry should assess whether the quality-assurance processes required for other

medical laboratories should apply to laboratories operated by physicians.

Current Status

The Ministry indicated that it had initiated discussions with the College of Physicians and Surgeons of Ontario regarding options for monitoring the quality of testing being performed in physicians' offices. While these discussions were ongoing at the time of our follow-up, the Ministry anticipated that this matter would be resolved by fall 2007.

MANAGEMENT AND REPORTING OF LABORATORY TESTS

We noted in our *2005 Annual Report* that the Ministry expected that the Ontario Laboratories Information System would be fully implemented by April 2007 at a cost of about \$84 million, and indicated that we would follow up on the status of the system. The system was expected to enable laboratory test information on individual patients to be accessed by all health-care and laboratory service providers directly involved with the patient. In addition, the system was expected to build a comprehensive information base to help manage and plan for laboratory service delivery, improve fiscal management of laboratory services, and provide timely utilization data to help develop best-practice guidelines for laboratory tests. At the time of our follow-up, the Ministry indicated that some project components (such as the rules-based on-line validation-of-services data) had been deferred pending future review, although the capability of laboratory ordering and viewing of results using the e-Health web portal was in the final stages of development, and its release strategy was also in the last phases. The Ministry indicated that total expenditures to March 31, 2007, were about \$58 million, with an additional \$26 million expected by the end of the 2007/08 fiscal year to complete the system development under way at the time of our follow-up.

PAYMENTS TO PRIVATE LABORATORIES

Recommendation

To help ensure that private laboratory services are acquired in an economical manner, the Ministry should periodically determine the actual cost of providing these services and utilize this information when negotiating payments for laboratory services.

Current Status

The Ministry noted that, at the time of our follow-up, it was developing terms of reference for a two-stage review of the cost of private laboratory services. The Ministry expects the first stage to be completed by the end of the 2007/08 fiscal year. It is to include obtaining cost data and funding approaches from other provinces, determining the cost of hospital laboratory services, and reviewing other fee-for-service structures in Ontario. Using this information, in the second stage, the Ministry is to assess the ability to determine the actual costs of private laboratory services in Ontario. The Ministry expects the second stage to proceed in the 2008/09 fiscal year in conjunction with the laboratory sector, with resulting recommendations to be used in determining a future payment agreement with private laboratories.

WELL-WATER TESTING

Test Results Reporting

Recommendation

To help ensure that individuals are aware of all potential contaminants in their well water, the Ministry should:

- *indicate that the water was not tested for other contaminants, including chemical contaminants, and therefore may be unsafe to drink even when there is no significant evidence of bacterial contamination; and*
- *indicate on the test results report where individuals can obtain information on having their water tested for other contaminants.*

Current Status

In July 2006, the Ministry revised both its well-water-sample instruction sheet and its reporting form to indicate that the sample was tested only for bacterial contamination—and not other contaminants, such as chemical contaminants—and therefore may be unsafe to drink even when there is no significant evidence of bacterial contamination. As well, the forms instruct individuals to contact their local public health unit for information on testing for other contaminants.

Rejection of Test Samples

Recommendation

To better assist Ontarians in the timely identification of well water that is unsafe to drink, the Ministry should re-examine its policy of rejecting and not testing water samples due to missing postal codes and/or telephone numbers.

Current Status

At the time of our follow-up, the Ministry indicated that, while a telephone number was still required on the well-water-testing requisition, the postal code was no longer a mandatory field, and that well-water samples were being tested even if the postal code was missing or incomplete. In addition, the Ministry has revised the well-water-collection kit instructions, which include information that individuals must submit with their water samples in order for them to be tested. As well, the Ministry commented that posters are displayed and one-page handouts are available at all water-collection-kit pick-up locations detailing information required for well-water testing. To determine the clarity of these instructions, amongst other things, in July 2006 the Ministry included a client feedback form in the well-water-collection kits. According to the Ministry, survey results for 2006 indicated that the majority of clients found the instructions clear. Final results from the survey for the 2007 calendar year are expected in early 2008.